

**Exhibit 5-12**  
**MODEL HEARING CONFIRMATION LETTER–**  
**Administrative Detention of Food**

(Region/OEIO Letterhead)

Date

Mr. John E. Smith  
XYZ, Inc.  
123 Smith Lane  
Anywhere, USA

Dear Mr. Smith:

I am confirming the information listed below discussed during our telephone conversation of today.

The hearing you requested on the appeal of the administrative detention of your article of food will be held on (date) at the (\_\_\_\_\_) district office, (street address, city, state, Zip Code) at (time) a.m/p.m.

The hearing will be a closed hearing because the proceedings constitute an open investigatory record. This means that only you, your counsel, witnesses, and employees as well as FDA representatives will be allowed to attend.

The regulations on administrative detention (21 CFR Part 1, subpart K) state that 21 CFR Part 16 will be followed in conducting the hearing. However, the regulations on administrative detention make the following exceptions to Part 16:

1. The detention order under 21 CFR 1.393, rather than the notice under 21 CFR 16.22(a), provides notice of opportunity for the hearing and is part of the administrative record of the regulatory hearing under 21 CFR 16.80(a).
2. A request for a hearing must be addressed to the FDA District Director in whose district the article of food involved is located.
3. The provision in 21 CFR 16.22(b), providing that a person not be given less than 3 working days after receipt of notice to request a hearing, does not apply.
4. The provision in 21 CFR 16.24(e), stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply.
5. 21 CFR 1.406, rather than 21 CFR 16.24(f), describes the statement that will be provided to an appellant where a detention order is based on classified information.
6. 21 CFR 1.404, rather than 21 CFR 16.42(a), describes the FDA employees, e.g., Regional Food and Drug Directors or other officials senior to a District Director, who preside at hearings.
7. The presiding officer may require that the hearing be completed within 1 calendar day, as appropriate.
8. 21 CFR 16.60(e) and (f) do not apply to the hearing. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing

- will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 4 hours of issuance of the report. The presiding officer will then issue the final agency decision.
9. 21 CFR 16.80(a)(4) does not apply to the hearing. The presiding officer's report of the hearing, and any comments on the report by the hearing participant under 21 CFR 1.403(h), are part of the administrative record.
  10. No party shall have the right under 21 CFR 16.119 to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final agency decision.
  11. If FDA grants a request for an informal hearing on an appeal of a detention order, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with 21 CFR Part 16, except that 21 CFR 16.95(b) does not apply to the hearing. With respect to the regulatory hearing on an appeal of a detention order, the administrative record of the hearing specified in 21 CFR 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. For purposes of judicial review under 21 CFR 10.45, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

I am authorized by 21 CFR 10.19 and 21 CFR 16.60(h) to waive, modify, or suspend any provision under 21 CFR Part 16. I am waiving, modifying, or suspending the following provisions:

1. 21 CFR 16.60(f), which requires the presiding officer to make a recommended decision with statement of reasons to the deciding official, is not applicable because I am the Deciding Official as well as the Presiding Officer in this instance.
2. Pursuant to 21 CFR 1.403(k), 21 CFR 16.95(b) does not apply.
3. 21 CFR 16.60(b), which provides that all parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing, is modified. Reasonable questioning will be allowed instead.

If feasible, at least one day before the hearing, you are to provide the District Director with written notice of, or a copy of, if the District Director could not reasonably be expected to obtain a copy, any published articles or written information you intend to present or rely upon at the hearing as required by 21 CFR 16.24(g).

Any written communication you forward or present to me must be sent by you to all other participants to the hearing as required by 21 CFR 16.44(c).

You are requested to provide at the hearing a brief summary of any lengthy documents you intend to present at the hearing.

If you have any additional questions on the procedures I will follow at the hearing, you may contact me at (phone number) prior to the hearing.

Sincerely yours,

Presiding Officer